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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,032	11/03/2003	Hani Sabbah	1059.00096	3424

7590 03/07/2006

Amy E. Rinaldo
KOHN & ASSOCIATES, PLLC
Suite 410
30500 Northwestern Highway
Farmington Hills, MI 48334

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,032

Applicant(s)

SABBAH ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3-5 and 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/19/04; 7/18/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I (claims 1 and 2) in the reply filed on 1/18/2006 is acknowledged.

The traversal is on the ground(s) that there is no serious burden in searching and examining all groups of claims. This is not found persuasive because different groups of claims are drawn to products and methods having different scope as claimed and, thus, the references that would be applied to one group of claims would not necessarily anticipate or render obvious the other group(s). Moreover, as to the question of burden of search, classification of subject matter is also an indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group. For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Upon applicants' request, further consideration and in order to promote efficiency of prosecution, the Group II claims 6 and 7 have been rejoined with the elected Group I (claims 1 and 2) as being drawn to similar methods.

Claims 3-5 and 8-14 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups of inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/18/2006.

Claims 1, 2, 6 and 7 are under examination in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,387,369 (Pittenger et al).

Claims are directed to a method of treating head failure, improving cardiac function and enriching or regenerating damaged myocardium wherein the method comprises step of administering stem cell products to a heart in need of treatment or to a damaged myocardium stem cell products. Some claims are further drawn to administering the stem cell products intravenously, intracoronary or directly to the heart.

US 6,387,369 (Pittenger et al) discloses a method for producing cardiomyocytes *in vivo* wherein the method comprises step of administering stem cell products such as MSCs directly to a heart (col. 6, line 31) or to directly into the damaged portion of myocardium (col. 2, lines 28-29). The cited patent teaches that MSC therapy can be provided by several route of administration including intravenously, intracoronary or directly to the heart (col. 4, lines 49-68). The cited reference anticipates the claimed invention because it teaches method comprising

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identical active step and identical structural elements as required by the claimed invention and, therefore, the effects are identical as disclosed and as intended.

Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomita et al. (IDS reference; Circulation, America heart Association. October 1998. Vol.98, NO. 17, Suppl. 27, pages 1-220).

Claims are directed to a method of treating heart failure, improving cardiac function and enriching or regenerating damaged myocardium wherein the method comprises step of administering stem cell products to a heart in need of treatment or to a damaged myocardium stem cell products. Some claims are further drawn to administering the stem cell products intravenously, intracoronary or directly to the heart.

The cited reference by Tomita et al. discloses a method of treating heart failure, improving cardiac function, enriching or regenerating damaged myocardium wherein the method comprises step of administering stem cell products such as mesenchymal stem cells (MSCs) directed to heart or to damaged myocardium. The reference teaches that transplantation of MSCs improved infarcted heart function. Thus, the cited reference anticipates the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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March 3, 2006

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER